

Applicants : Tania C. Sorrell
Serial No. : 10/081,838
Filed : February 21, 2002
Page 12

Amendments to the Drawings

No amendments are proposed to the drawings.

Applicants : Tania C. Sorrell
Serial No. : 10/081,838
Filed : February 21, 2002
Page 13

Remarks

Reconsideration and allowance of the present application in view of the amendments above and comments which follow are respectfully requested.

In the Office Action dated July 6, 2005, the Examiner stated that claims 1-9, 15-27, 33-45, and 51-54 were elected and that a complete reply must include cancellation of non-elected claims 10-14, 28-32, and 46-50. These latter non-elected claims have been cancelled.

The Examiner rejected Claims 1-9, 15-27, 33-45, and 51-54 as being allegedly obvious over Somorjai et al. (Magnetic Resonance in Medicine (1995) Vol. 33, pages 257-263; PTO Form 1449 Reference 21), in view of Delpassand et al. (Journal of Clinical Microbiology (1995) May, page 1258-1262; PTO Form 1449 Reference 5) for the reasons set forth in the previous Office Action.

The Examiner stated that applicant's argument distinguishing Delpassand was not supported by the claim language. Without agreeing with the Examiner's position, but solely to advance prosecution, applicant has further amended claims 1, 19 and 37 to more clearly recite that the claimed method enables classifying microorganisms of unknown species within the same genus into known species within the same genus. The presently claimed invention enables one to discriminate between closely related species, i.e., species within the same genus, by using a linear discriminate analysis classifier.

Applicants respectfully traverse the rejection made on obviousness grounds based on the Delpassand et al and Somorjai references.

The Delpassand reference discusses obtaining MR spectra from a few widely different genera of bacteria, namely, *Escherichia coli*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Enterococcus faecalis*. The five bacteria listed are different genera, and no two of them are in the same genera. Moreover, in each case, the genera was identified

Applicants : Tania C. Sorrell
Serial No. : 10/081,838
Filed : February 21, 2002
Page 14

by determined by picking the two most prominent peaks in the spectra of each (by visual inspection only) to distinguish between genera, and not within genera. They acknowledged that more isolates would have to be studied to verify the method, and they did not use a statistical classification strategy for the analysis.

With regard to differentiation between species, they compared the spectrum of only one strain (isolate) of *Shigella flexneri* with one strain of *Shigella sonnei*. They also claimed in the discussion without showing any data that *Enterococcus faecalis* could be distinguished from *Enterococcus faecium* by NMR spectroscopy. Neither of these claims is valid on the basis of testing only one strain (*Shigella*) and showing no data (*Enterococcus*). Biological variation occurs between bacterial strains, which is why substantial numbers showing reproducible characteristics are needed to build up a reliable, fully discriminatory, database to enable one to reliably distinguish one species from another in the same genera.

Applicant urges that it would not have been obvious to combine Delpassand's approach with the SCS method of Somorjai because the successful introduction of SCS to the identification of bacteria requires the accumulation of a large data set of closely and distantly related organisms, and such methodology would not have occurred to one of ordinary skill in the art. The Delpassand reference used only statistically non-significant number of strains and used only visual inspection, and nowhere suggested the use of a statistical classifier. Further the SCS method of Somorjai did not disclose the concept of discriminating closely and distantly related species within the same genus. Applicant urges that the suggested combination of Delpassand with Somorjai was arrived at through hindsight, using applicant's invention as a guide, which is improper.

In the Office Action, the Examiner stated that applicant's argument, that it would not have been obvious to combine Delpassand with Somorjai, because the successful introduction of SCS to identify bacteria requires the accumulation of large data sets, was not persuasive, as the claims are not limited to large data sets of closely and distantly related organisms. Applicant urges that the claims need not recite large data sets of closely and distantly related organisms to make this argument about the impropriety of combining references. Applicant's argument was made in

Applicants : Tania C. Sorrell
Serial No. : 10/081,838
Filed : February 21, 2002
Page 15

response to a position taken by the Examiner that it would be obvious to combine an SCS method of Somorjai with an identification system of Delpassand to arrive at applicant's claimed system of using SCS to identify bacteria. To rebut the position of obvious (or motivation to combine Somorjai with Delpassand) applicant states that one skilled in the art would not be motivated to combine Somorjai with Delpassand to identify bacteria because the identification of bacteria within species requires the accumulation of large data sets and there has been no showing by the Examiner that one skilled in the art would have been motivated to accumulate a large data set using SCS, to arrive at applicant's claimed invention. Accordingly, it would not have been obvious to combine Somorjai with Delpassand.

In the Advisory Action dated November 4, 2005, the Examiner stated that the amendments to the claims adding "within the same genus" include new matter. The applicant respectfully addresses the Examiner's attention to page 5, lines 6-7 ("enabling the identification, preferably down to the species group or species level, of various microorganisms"); and page 7, lines 5-7 ("for example, five pathogenic *Candida* species as well as the two varieties [of] the pathogenic yeast species *Cryptococcus neoformans* (var. *gallii* and var. *neoformans*) can be identified according to the invention."). Applicant submits that these citations provide adequate support for the amendatory language.

Applicants : Tania C. Sorrell
Serial No. : 10/081,838
Filed : February 21, 2002
Page 16


Other than the three month extension fee which is being submitted, no other fee is believed to be due in connection with this Amendment. If any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account Number 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

 1/6/06
Peter J. Phillips Date
Reg. No. 29,691


Peter J. Phillips
Registration No. 29,691
Attorney for Applicant
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400